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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0009; FRL-9366-6]

Fluazinam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazinam in or on melon subgroup 9A and pepper/eggplant subgroup 8-10B, associated with pesticide petition (PP) 1E7959; and soybean, seed and soybean, hulls, associated with PP 2F7977. Interregional Research Project Number 4 (IR-4) and ISK Biosciences Corporation requested the tolerances associated with PPs 1E7959 and 2F7977, respectively, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0009, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading

Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: *Nollen.Laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0009 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0009, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For-Tolerance

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7959) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.574 be amended by establishing tolerances for residues of the fungicide fluazinam, (3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), in or on fruiting vegetables group, pepper/eggplant subgroup 8-10B at 0.10 parts per million (ppm); and cucurbit vegetables, melon subgroup 9A at 0.08 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by ISK Biosciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*.

Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Additionally, in the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a PP 2F7977 by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.574 be amended by establishing tolerances for residues of the fungicide fluazinam in or on soybean, seed at 0.01 ppm; and soybean, hulls at 0.02 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has revised the tolerances for several commodities. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure

of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluazinam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazinam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Following subchronic and chronic exposure to fluazinam, the liver appeared to be a primary target organ in rats, dogs, and mice. Signs of liver toxicity included changes in clinical chemistry (increased serum alkaline phosphatase and aspartate aminotransferase), increased absolute and/or relative liver weights, increased incidences of gross lesions (pale, enlarged, pitted, mottled, accentuated markings), and a variety of histopathological lesions. Treatment-related effects were also observed in other organs following subchronic and chronic exposure to fluazinam, but these effects were not consistently noted in all three species or in all studies in a given species. In a subchronic inhalation

toxicity study in rats, pulmonary effects were observed at the mid and high doses. These effects included dose-related increases in lung/bronchial weights and increased incidences of alveolar macrophages and peribronchiolar proliferation in both sexes.

In the developmental toxicity study in rabbits, treatment-related maternal effects (decreased food consumption and increased liver histopathology) were noted in the absence of fetal effects. In the 2-generation rat reproduction study, decreased pup weight gain was seen at the highest dose tested, in the presence of decreased food consumption and liver histopathology in parental animals. In a developmental toxicity study in rats, fetal effects included decreases in body and placental weights, increased incidences of facial/palate clefts, diaphragmatic hernias, delayed ossification in several bone types, increases in late resorptions, as well as evidence of a greenish amniotic fluid and post-implantation loss. Maternal effects, including decreases in body weight gain/food consumption and increases in water consumption and urogenital staining, were observed at the same dose level. In the rat developmental neurotoxicity (DNT) study, effects in pups (including decreases in body weight/body weight gain and delayed preputial separation) were noted in the absence of maternal toxicity.

In an acute neurotoxicity study in rats, effects included decreases in motor activity and soft stools; these effects were considered to be due to systemic toxicity and not a result of frank neurotoxicity. No signs of neurotoxicity were observed in two subchronic neurotoxicity studies in rat up to the highest dose tested. A neurotoxic lesion described as vacuolation of the white matter of the central nervous system was observed in subchronic and chronic studies in mice and dogs; however, this lesion was found to be reversible and is attributed to an impurity. Based on the level of this impurity in

technical grade fluazinam, the risk assessment for the parent compound is considered protective of the effects noted. In an immunotoxicity study in mice, significant suppressions of anti-sheep red blood cell antibody-forming cell assay response were demonstrated at the highest dose tested.

In a rat carcinogenicity study, there was some evidence that fluazinam induced an increase in thyroid gland follicular cell tumors in male rats. There were statistically significant positive trends for thyroid gland follicular cell adenocarcinomas and combined follicular cell adenomas/adenocarcinomas. The incidences of thyroid gland adenomas seen at 100 ppm (3.8 mg/kg/day) and adenocarcinomas at 1,000 ppm were slightly outside their respective ranges for the historical controls. However, this increased incidence of thyroid tumors at 100 ppm was not observed in male rats in another chronic study. Further in the rat carcinogenicity study where these effects were seen, the animals in the lower dose groups were only microscopically examined for thyroid lesions if abnormalities were observed in that organ at gross necropsy and therefore, the incidences of thyroid tumors in the lower dose groups may have been somewhat misleading (too high). In one mouse carcinogenicity study, clear evidence of a treatment-related increase of hepatocellular tumors was observed in male mice; in another mouse carcinogenicity study, there was equivocal evidence that fluazinam may have induced an increase in hepatocellular tumors in male mice. There was no evidence of statistically significant tumor increases in female mice or rats in any study and no evidence of mutagenic activity in the submitted mutagenicity studies for fluazinam. EPA has classified fluazinam as having suggestive evidence of carcinogenicity. Due to the equivocal and inconsistent nature of the cancer response in the rat and mouse studies, the

Agency determined that quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluazinam.

Specific information on the studies received and the nature of the adverse effects caused by fluazinam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document, "Fluazinam. Human Health Risk Assessment to Support New Uses on Soybeans, the Melon Subgroup (9-A), and the Pepper/Eggplant Subgroup (8-10B), and to Support Registration Review" at pages 43-49 in docket ID number EPA-HQ-OPP-2012-0009.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of

exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fluazinam used for human risk assessment is shown in Table 1 of this unit. To assess short-term dermal exposure, the dermal toxicity and dermal absorption studies were used to determine a refined dermal equivalent dose (RDD). To calculate a RDD, *in vitro* results using rat skin are corrected for any differences between *in vitro* and *in vivo* absorption rates and species differences between rats and humans. This refinement in dermal absorption is important because absorption by human skin is usually lower than that by rat skin. Accordingly, the combined use of the data from three dermal absorption studies and two testing systems offers greater precision in estimating human dermal absorption, which strengthens the reliability of the dermal risk assessment.

Table 1.--Summary of Toxicological Doses and Endpoints for Fluazinam for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 7 milligrams/kilogram/day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.07 mg/kg/day aPAD = 0.07 mg/kg/day	Developmental Toxicity Study- Rabbits LOAEL = 12 mg/kg/day based on increased incidence of total litter resorptions and possible increased incidence of fetal skeletal abnormalities

Acute dietary (General population including infants and children)	NOAEL = 50 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute Neurotoxicity-Rats LOAEL = 1000 mg/kg/day based on decreased motor activity and soft stools on day of dosing
Chronic dietary (All populations)	NOAEL = 1.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.011 mg/kg/day cPAD = 0.011 mg/kg/day	Co-critical: Carcinogenicity-Mice LOAEL = 10.7 mg/kg/day based on liver histopathology and increased liver weight Chronic Dog LOAEL = 10 mg/kg/day based on marginal increases in the incidence of nasal dryness in females and the incidence/severity of gastric lymphoid hyperplasia in both sexes
Dermal short-term (1 to 30 days)	Dermal study NOAEL= 10 mg/kg/day Refined Dermal absorption rate = 2.44% UF_A = 10x UF_H = 10x FQPA SF = 1x	RDD*= 24.4 mg/kg/day LOC for MOE = 100	21-Day Dermal Toxicity-Rats LOAEL= 100 mg/kg/day based on liver effects (increased AST and cholesterol levels)
Cancer (Oral, dermal, inhalation)	Non-linear RfD approach was used to assess cancer risk.		

FQPA SF = Food Quality Protection Act Safety Factor.
LOAEL = lowest-observed-adverse-effect-level.
LOC = level of concern.
mg/kg/day = milligram/kilogram/day.
MOE = margin of exposure.
NOAEL = no-observed-adverse-effect-level.
PAD = population adjusted dose (a = acute, c = chronic).
RfD = reference dose.
UF = uncertainty factor.
UF_A = extrapolation from animal to human (interspecies).
UF_H = potential variation in sensitivity among members of the human population (intraspecies).
*A Refined Dermal Equivalent Dose (RDD) of 24.4 mg/kg/day was calculated using the dermal POD and dermal absorption data.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fluazinam, EPA considered exposure under the petitioned-for-tolerances as well as all existing fluazinam tolerances in 40 CFR 180.574. EPA assessed dietary exposures from fluazinam in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for fluazinam. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA utilized tolerance-level residues, 100 percent crop treated (PCT) for all commodities, and used DEEM default processing factors, when appropriate.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA utilized tolerance-level residues for all commodities except apple (for which the average field trial residue value was used), assumed 100 PCT for all commodities, and used DEEM default processing factors, when appropriate.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based

on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to fluazinam. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The residues of concern in drinking water for risk assessment are parent fluazinam and its degradates, including DCPA, CAPA, DAPA, HYPA, and AMPA. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluazinam and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluazinam and its degradates. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fluazinam and its degradates for surface water are estimated to be 226 parts per billion (ppb) for acute exposures and 37.8 ppb for chronic exposures. For ground water, the EDWCs are estimated to be 0.404 ppb for both acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration values of 226 ppb and 37.8 ppb were used to assess the contribution to drinking water in the acute and chronic dietary risk assessments, respectively.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fluazinam is currently registered for following use that could result in residential exposures: on turf at golf courses only. EPA assessed potential residential short-term post-application dermal exposure from individuals, including adults, youth (11 to <16 years old), and children (6 to <11 years old), playing golf on treated turf. The short- and intermediate-term toxicological endpoints for fluazinam are the same for the dermal route of exposure. As a result, only the short-term dermal exposure was assessed. The resulting short-term risk estimates are considered to be protective of intermediate-term exposure and risk.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found fluazinam to share a common mechanism of toxicity with any other substances, and fluazinam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluazinam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for fluazinam includes rat and rabbit developmental toxicity studies, a 2-generation reproductive toxicity study in rats, and a DNT study in the rat. There was no evidence of increased quantitative or qualitative susceptibility in the rabbit developmental toxicity study or the rat 2-generation reproductive toxicity study; however, evidence of increased qualitative susceptibility of fetuses was observed in the rat developmental toxicity study and evidence of increased quantitative susceptibility of fetuses was observed in the rat DNT study.

In the developmental toxicity study in rats, fetal effects (increased incidences of facial/palate clefts and other rare deformities in the fetuses) were observed in the presence of minimal maternal toxicity (decreased body weight gain and food consumption, and increased water consumption and urogenital staining). In the rat DNT study, decreases in body weight/body weight gain and a delay in completion of balano-preputial separation were observed in pups in the absence of maternal effects, suggesting increased quantitative susceptibility of the offspring.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluazinam is complete.

ii. There is no evidence that fluazinam results in increased susceptibility in *in utero* rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study; however, increased qualitative susceptibility was noted in the rat developmental toxicity study. The degree of concern for the observed effects is low

because fetal effects were observed only at the highest dose tested in the presence of maternal toxicity, and there is a clear NOAEL for the fetal effects seen. Additionally, the NOAEL (50 mg/kg/day) identified in the developmental toxicity study in rats is significantly higher than the NOAEL used (7 mg/kg/day) to establish the aRfD for females 13-49. Therefore, the aRfD is protective of any potential developmental effects and there are no residual uncertainties for prenatal and/or postnatal toxicity.

Additionally, while a DNT study in rat did not show evidence of neurotoxicity, the study showed evidence of increased quantitative susceptibility of offspring. Although the NOAEL for this study (2 mg/kg/day) is lower than that used for the aRfD for females 13-49 (7 mg/kg/day), the effects noted in the DNT study are considered to be postnatal effects attributable to multiple doses; therefore, the study endpoint is not appropriate for acute dietary exposures. The cRfD (0.011 mg/kg/day) is based on a lower NOAEL (1.1 mg/kg/day), and is considered to be protective of potential developmental effects. Therefore, the degree of concern is low for the observed effects and there are no residual uncertainties with regard to prenatal and/or postnatal neurotoxicity.

iii. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments were performed based on 100 PCT for all commodities. Additionally, the acute assessment is based on tolerance-level residues for all commodities, and the chronic assessment is based on tolerance-level residues for all commodities except apple (for which the average field trial value was used). These assumptions result in high-end estimates of dietary exposure**.** EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to fluazinam in drinking water. EPA used similarly conservative

assumptions to assess post-application exposure of children. Incidental oral exposure of toddlers is not expected from any use pattern for fluazinam. These assessments will not underestimate the exposure and risks posed by fluazinam.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluazinam will occupy 28% of the aPAD for females 13-49 years old; and 21% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure for the general population, including infants and children.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazinam from food and water will utilize 51% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluazinam is not expected.

3. *Short-term risk* . Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluazinam is currently registered for uses that could result

in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluazinam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 730 for children 6-<11 years old, 880 for youth 11-<16 years old, and 970 for adults. Because EPA's level of concern for fluazinam is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Based on the discussion in Unit III.C.3., short-term risk estimates are considered to be protective of intermediate-term exposure and risk.

5. *Aggregate cancer risk for U.S. population*. Based on the discussion in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluazinam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromatography with electron capture detection (GC/ECD) method (6148-94-0170-MD-001) is available to enforce fluazinam tolerances on plant commodities. An adequate enforcement method for the determination of AMGT is also

available. The method is a high performance liquid chromatography with ultraviolet detection (HPLC/UV) enforcement method entitled “Method Evaluation for the Analysis of AMGT in Grapes.”

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fluazinam on the commodities associated with this action.

C. Response to Comments

EPA received several comments to the docket, EPA-HQ-OPP-2012-0009; however, only one of these public submissions was in response to the Notice of Filing for

PP 1E7959, while the remaining comments pertained to unrelated petitions in the **Federal Register** notice. For PP 1E7959, the commenter stated that no residue should be allowed for fluazinam and that they do not support manufacture or use of this product. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. In addition, the commenter included several adverse effects they believed were seen in animal toxicology studies for fluazinam. EPA has found that there is a reasonable certainty of no harm to humans after considering the toxicological studies and the exposure levels of humans to fluazinam.

D. Revisions to Petitioned-For-Tolerances

Based on the data supporting the petitions, EPA revised the proposed tolerances on melon subgroup 9A from 0.08 ppm to 0.07 ppm; pepper/eggplant subgroup 8-10B from 0.10 ppm to 0.09 ppm; and soybean, hulls from 0.02 ppm to 0.05 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of fluazinam, (3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), in or on melon subgroup 9A at 0.07 ppm; pepper/eggplant subgroup 8-10B at 0.09 ppm; soybean, seed at 0.01 ppm; and soybean, hulls at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 26, 2012

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.574, alphabetically add the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.574 Fluazinam; tolerances for residues.

(a) *General.* (1) * * *

Commodity	**Parts per million**
* * *	* *
Melon subgroup 9A	0.07
* * *	* *
Pepper/eggplant subgroup 8-10B	0.09
* * *	* *
Soybean, seed	0.01
Soybean, hulls	0.05
* * *	* *

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